DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. Food and Drug Administration Los Angeles District Office 19701 Fairchild, (949) 608-2900 Industry Information: www.fda.gov/oc/industry	03/26/2018 - 04/03/2018
	FEI NUMBER 3005256616

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Justin Y. Chen, Owner

FIRM NAME	STREET ADDRESS
Chen Shwezin DBA Park Compounding Pharmacy	4333 Park Terrace Drive, #160
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Westlake Village, CA 91361	producer of non-sterile drug products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1
Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, your firm conducted potency testing on three finished drug products during the previous eight months which were supposed to represent all distributed products and dosage forms. Product selection did not consider factors such as difficulty to produce or the relative amount of active ingredient. Examples of drug products distributed without adequate assurance they met their labeled strength claims include:
- Lidocaine + Tetracaine 23+7% cream, 60 mL, lot 02072018@12
- Diclofenac suppository, 100 mg, lot 01042018@13
- Trichloroacetic Acid 35% solution, 60 mL, lot 03142018@16
- Cantharidin Plus liquid, 100 mg/10 mL, lot 01192018@13
- Benzocaine + Lidocaine + Tetracaine 20+8+4% Lipoderm, 30 gm, lot 03132010@32

OBSERVATION 2
Equipment and utensils are not cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, there were no written cleaning, sanitization, or maintenance procedures. I observed equipment designated clean was soiled. There was no documented evidence cleaning agents effectively removed drug products residues, and that cleaning agents were completely removed.

A) Capsule plates designated clean and ready for production use contained powder residue on the inner edges of the slots which directly contact open capsules during filling. There was visible, loose powder on the upper work surfaces and outer housing of three of (b) (4) capsule machines.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Nicholas L. Hunt -S Digitally signed by Nicholas L Hunt -S Date: 2018.04.03 17:19:51 -07'00'	Nicholas L. Hunt, Investigator	04/03/2018

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B) I observed an apparent hair stuck to residue on one roller of an (b) (4) ointment mill which was designated clean and ready for production use.

C) 5 o[(b) (4)] spatulas used to transfer finished drug products into their final container-closure had several sections missing from the bottom edge which created a rough, uneven surface. Your firm could not explain where the missing pieces were located. I observed the spatulas available for use in the production area, and production personnel confirmed they use the spatulas regularly.

D) (b) (4) powder containment hoods used during topical and oral solid dosage drug production were damaged and not easily cleanable. The seams were sealed with black duct tape and clear packaging tape. There were several large cracks sealed with tape, and there was powder residue visible on the exposed adhesive. Both hoods were designated clean and ready for use.

E) I watched personnel wash encapsulation components and various utensils used to produce hazardous and non-hazardous drug products. They used (b) (4) water and (b) (4) . There was no documentation the cleaning process and cleaning agent effectively removed all drug product residues. Personnel wiped encapsulation components with (b) (4) but did not sanitize any other utensils.

F) Your firm used (b) (4) in its residential dishwasher. The dishwasher cleaned glassware and plastic jars from the (b) (4) mixer which were used to produce hazardous and non-hazardous drug products. There was no documentation the cleaning process and cleaning agent effectively removed all drug product residues.

OBSERVATION 3
Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established, written, and followed.

Specifically, the tool used to (b) (4) compress powder into capsules was cleaned, sanitized, and then stored on a soiled, wet cloth for approximately (b) (4) hours. The tool was upright on the protrusions which directly contact powder inside the capsules.

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OBSERVATION 4
Each lot of a component that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

Specifically, your firm did not perform microbiological or ionic testing to ensure water quality met applicable standards for non-sterile drug production. Production personnel used (b) (4) Water to produce water based suspensions. Water for drug production was supplied in (b) (4) and dispensed from a water cooler in the employee break room. I observed employees fill their personal water bottles using the same water cooler. (b) (4) was used to produce Trichloroacetic Acid 35% solution, 60 mL, lot 03142018@16.

OBSERVATION 5
Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, sampling plans, and test procedures designed to assure drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, your firm did not establish specifications for acceptable levels of microorganisms or conduct microbial enumeration tests for non-sterile drug products. Examples of drug products distributed without microbial enumeration information include:
- Lidocaine + Tetracaine 23+7% cream, 60 mL, lot 02072018@12
- Diclofenac suppository, 100 mg, lot 01042018@13
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